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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,728	06/19/2001	Clifford J. Dwyer	CRD-0940	3625

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EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,728

Applicant(s)

DWYER ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-9, and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 6, 2003 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-2 and 6-7, filed June 6, 2003 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 3-5 and 8-15, filed June 6, 2003 have been fully considered but they are not persuasive. Applicant has argued that Wilson et al. (USPN 6,425,898 B1) cannot be used in making an obviousness type rejection under 35 U.S.C. 103(a) because Wilson qualifies as prior art under 35 U.S.C. 102(e) and at the time the invention was made, the invention was owned by the same person, Cordis Corporation, through an Assignment made in the parent case (09/631,002). The examiner disagrees. Assignment of an original application carries title to a divisional, continuation, or reissue application only. See MPEP 201.12. The current application is a CIP of parent application 09/631,002. Therefore according to MPEP 306, in the case of a CIP, a prior assignment of the original application is not applied to the CIP because the assignment recorded against the original application gives the assignee rights to only the subject matter common to both applications. CIP applications require a new

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assignment if they are to be issued to an assignee. Therefore, the argument is not found persuasive and the rejection still stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,425,898 B1, cited in previous office action) in view of Truckai (USPN 5,176,660, cited in previous office action). Referring to claims 1 and 4, Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10) having a guidewire lumen (28), a stent bed (24), a sheath (40) having an enlarged section (col.4, lines 35-38; fig.5) coaxial with the stent bed, the sheath including an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70). Wilson discloses a delivery apparatus with a wire reinforced sheath substantially as claimed, however does not disclose, wires having a rectangular cross section and dimensions for such wires. Truckai teaches a layered delivery sheath (catheter, 10) having flat wire reinforcement (16) with rectangular cross-sections (fig.5) and dimensions similar to the dimensions claimed (col.2, lines 60-61; col.4, lines 1-5, 39), in order to increase the stiffness of the sheath while minimizing profile (col.2, lines 15-21, 42-43; col.4, lines 1-7; col.5, lines 11-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Wilson's wire reinforced sheath with

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Truckai's geometric teaching flat *rectangular* wires used in sheaths, in order to provide a smooth and stiff delivery sheath having a minimized profile.

Referring to claim 2, Wilson discloses a reinforcement layer (70), which extends between the inner and outer layers (fig. 8).

Referring to claim 5, Wilson has shown a wire arranged in a braided configuration (col. 7, lines 65-67).

Referring to claims 6 and 7, Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col. 7, lines 65-66).

Claims 8-9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,425,898 B1, cited in previous office action) in view of Kocak (USPN 4,705,511, cited in previous office action). Referring to claims 8, 11, and 15, Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10) having a guidewire lumen (28) and a stent bed (24), a sheath (40) having an enlarged section (col. 4, lines 35-38; fig. 5) coaxial with the stent bed, the sheath formed from an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70). Wilson does not however, the reinforcement layer having wires with a rectangular cross section with dimensions and a lubricious coating on an inner polymeric layer. Kocak teaches in the same field of endeavor, a wire reinforcement layer having a rectangular cross section with specific dimensions and made of stainless steel in order to provide a low, smooth, profile and increased flexibility (fig. 5; 140; col. 7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kocak's geometric teaching of using a dimensioned

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rectangular cross section stainless steel wire reinforcement layer in a sheath, with Wilson's sheath reinforcement layer, in order to provide a low smooth profile with flexibility. Kocak teaches in the same field of endeavor, a delivery sheath (38, 138) for introducing catheters and medical devices to the vascular system (col.4, lines 15-16), the sheath having a wire reinforcing layer (40, 140), polymeric layers (42, 142) and additional lubricous coating (41, 141), wherein the purpose of the coating is to provide a smooth, low friction surface (col.5, lines 56-61). Kocak discloses coating materials comprising PTFE or silicone (col.5, lines 65-67; col.3, lines 8-17; col.4, line 59; col.4, lines 63-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kocak's teaching of lubricous coating such as silicone on a delivery sheath, with Wilson's delivery sheath in order to provide a sheath with a smooth, lubricious, low friction surface.

Referring to claim 9, Wilson discloses a reinforcement layer sandwiched between an inner and outer polymeric layer and extending the length of the sheath (fig.8).

Referring to claim 12, Wilson discloses wire reinforcement arranged in a braided configuration (col.7, lines 65-67).

Referring to claims 13 and 14, Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col.7, lines 65-66).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER